

*Page 1 of (2)*

**510(k) Summary**  
**ArthroCare Corporation**  
**ENT® Plasma Wands™**

*K 070374*

**APR 25 2007**

**General Information**

**Manufacturer:** ArthroCare, Corporation  
680 Vaqueros Avenue  
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:** Valerie Defiesta-Ng  
Director, Regulatory Affairs  
(408) 736-0224

**Date Prepared:** February 7, 2007

**Device Description**

**Trade Name:** ENT® Plasma Wands™

**Generic/Common Name:** Electrosurgical Device and Accessories  
Electrosurgical Cutting and Coagulation Device and  
Accessories (21 CFR 878.4400)

**Predicate Devices**

ArthroCare ENT Plasma Wands  
K014290, cleared March 28, 2002  
K063538, cleared December 1, 2006

K 040374

Page 2 of 2

#### Intended Use

The proposed indications statement for the ArthroCare ENT Plasma Wands is for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoideectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy (including palatine tonsils)
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

#### Product Description

The ArthroCare ENT Plasma Wands are bipolar, single use, high frequency electrosurgical devices designed for specific indications in otorhinolaryngology (ENT) surgery.

#### Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials incorporated, product specifications, and energy requirements of those systems. The expansion of the indications to include specific ENT procedures does not raise any new issues of safety or efficacy.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 25 2007

Arthrocare Corporation  
% Ms. Valerie Defiesta-Ng  
Director, Regulatory Affairs  
680 Vaqueros Avenue  
Sunnyvale, California 94085-3523

Re: K070374

Trade/Device Name: ENT® Plasma Wands™

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: GEI

Dated: February 7, 2007

Received: February 8, 2007

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

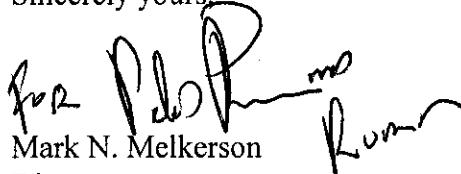
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Valerie Defiesta-Ng

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

Device Name: ENT® Plasma Wands™

510(k) Number: K070374

### Indications for Use:

The ArthroCare ENT Plasma Wands is for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy (including palatine tonsils)
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

Prescription Use \_\_\_\_\_ X OR Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K070374